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INFORMATIONAL BULLETIN

WASTE PHARMACEUTICALS

Hazardous Waste Determination Guidance

Hospitals, medical clinics, doctors, dentists, veterinarians, and other health care facilities generate several types of wastes. These include hazardous waste identified under the federal Resource Conservation and Recovery Act (RCRA), non-RCRA hazardous waste, medical waste, and waste pharmaceuticals. When SB 1966 became effective in 1997, waste pharmaceuticals that are classified as non-RCRA (California only) hazardous waste were included under the definition of ***Medical Waste.*** These wastes must be handled and disposed of as medical waste according to the requirements of the California Medical Waste Management Act (MWMA), Sections 117635 (g), 117747, and 118222 (b), California Health and Safety Code.

Some common questions being asked by health care facilities are:

1. What is a waste pharmaceutical?
2. How do I know if the waste pharmaceutical is a RCRA hazardous waste?
3. How do I know if the waste pharmaceutical is a non-RCRA hazardous waste?
4. What can I throw in the trash or pour down the drain?

It is important to note that **it is the responsibility of the waste generator to determine if the waste pharmaceutical is a hazardous waste.** This guidance document will help facilities determine if waste pharmaceuticals they generate must be managed as hazardous waste.

1. What is a waste pharmaceutical?

The MWMA, §1177477 defines *pharmaceutical* as a prescription or over-the-counter human or veterinary drug not regulated pursuant to the Resource Conservation and Recovery Act (RCRA) or the Radiation Control Law. §117635 (g) of the MWMA includes waste, which is "hazardous" only because it is comprised of pharmaceuticals, in the definition of biohazardous waste § 118275 (g).The MWMA indicates that pharmaceutical waste is to be separated from other medical waste, placed in a container labeled "INCINERATE ONLY" and incinerated at a permitted medical waste treatment facility.

SB 1966 was introduced by Senator Cathie Wright. Senator Wright wrote a letter dated August 27, 1996 to Bill Lockyer, the President Pro Tempore of the Senate to clarify the intent of the bill. The letter provides an important clarification regarding the intended extent of pharmaceutical waste regulated by this act. The third paragraph of Senator Wright's letter reads as follows:

> "*SB 1966 would not affect the regulation of that pharmaceutical waste which is not regulated as hazardous waste under California statute. Such pharmaceutical waste will continue to be regulated as solid waste pursuant to the California Integrated Waste Management Act."*

2. How do I know if the waste pharmaceutical is a RCRA hazardous waste?

Title 22 of the California Code of Regulations (CCR), Section 66261.33 states a discarded listed material that is manufactured or formulated for commercial use and which consists of a commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is a **sole active ingredient,** is a RCRA listed hazardous waste.

Therefore, if a pharmaceutical has one sole active ingredient and that material is listed in either the P or U lists, it is a listed RCRA hazardous waste. In addition to being a listed hazardous waste, a waste pharmaceutical can also be a RCRA hazardous waste if it exhibits any of the characteristics of 66261.21 (Ignitability), 66261.22 (a)(1) or (2) (Corrosivity), 66261.23 (Reactivity), or 66261.24 (a)(1) Toxicity.

3. How do I know if the waste pharmaceutical is a non-RCRA hazardous waste?

Per CCR Title 22, Chapter 11, Appendix X, if a waste pharmaceutical is formulated with a material listed in Appendix X and it has been determined to not be a RCRA hazardous waste (not listed in 66261.33 or 66261.24 (a)(1) or to not meet the hazardous characteristics (I, C, R, T), it is **presumed** to be a non-RCRA hazardous waste.

4. What can I throw in the trash or pour down the drain?

Per CCR Title 22, 66262.11 (b), if a pharmaceutical waste is presumed to be a non-RCRA hazardous waste, the generator may determine that it is not hazardous by applying knowledge of the hazardous characteristic of the pharmaceutical waste in light of the materials contained and the characteristics set forth in 66261.22 (a)(3) or (4) and 66261.24 (a)(2) through (a)(8). To make this determination, the generator may use information known from their knowledge of the waste or gained information from an analysis of the waste. Should the generator have general knowledge that the waste does not have RCRA or non-RCRA hazardous characteristics (i.e. aspirin); it may be disposed of as a solid waste.

Two categories of Hazardous Waste

I. Characteristic Waste	II. Listed Waste
Ignitable	**F List** -Hazardous waste, non-specific sources
Corrosive	**K List** Hazardous waste, specific sources
Reactive	**P List** Acute hazardous Waste
Toxic	**U List** Toxic Hazardous Waste

Examples of RCRA Hazardous Pharmaceutical Waste

The National Institutes of Health recently looked at the 39 drugs most commonly used (both on patients and experimentally in laboratories) and determined that the following are listed as hazardous waste: Cytoxin (U058), U059 Daunomycin (U059); Melphalan (U150), Mytomycin C (U010), Streptozotocin (U206).

Common scenarios found in facilities managing pharmaceutical wastes

Scenario #1. A nurse administers/injects epinephrine to a patient. After the proper dose is injected, excess epinephrine and epinephrine residues remain in the syringe. Is the epinephrine remaining in the syringe a P-listed hazardous waste when the syringe is discarded?

Answer: The epinephrine in the discarded syringe would **not** be classified as a listed hazardous waste. The P-list of hazardous waste applies to unused discarded commercial chemical products. Commercial chemical products are defined as commercially pure grades and technical grades of the listed chemicals or chemical formulations in which the listed chemical is the sole active ingredient, **which have not been used for their intended purpose.** Drug residues often remain in dispensing instruments after the instrument is used to administer medication. Fed EPA considers such residues remaining in a dispensing instrument to have been used for their intended purpose. The epinephrine remaining in the syringe, therefore, is not a commercial chemical product and not a P042 hazardous waste. Discard the syringe into a sharps container.

Scenario #2. The pharmacy of a hospital has a large bottle of nitroglycerine pills that have exceeded its shelf life. The pills contain a low percentage of nitroglycerine, with inert ingredients making up the remainder of the content. Do the pills have to be disposed of as a hazardous waste?

Answer: Prior to August 14, 2001, nitroglycerin pills had to be managed as a RCRA hazardous waste because the sole active ingredient was listed in subpart D as a "P" listed waste (Reactivity). Effective August 14, 2001 if a subpart D hazardous waste listed for ignitibility, corrosivity, or reactivity no longer exhibits any of these characteristics; it is not a hazardous waste. Nitroglycerin pills do not exhibit any characteristics of a hazardous waste. Therefore, they are not a RCRA hazardous waste. Also, per the DHS Management of Pharmaceutical Medical Waste Document of 10/15/2002, it is permissible to manage pharmaceutical nitroglycerin as a solid waste.

Scenario #3. A chemotherapy drug is mixed with diluents, such as water or saline solution. If any excess of the drug is generated, does it have to be managed as a hazardous waste? Does the answer change based on the amount that the drug is "diluted"?

Answer: If a chemotherapy drug is mixed with diluents, the excess diluted or undiluted amount to be discarded is **unused commercial chemical product.** If the excess unused commercial chemical product is listed in 40 CFR 261.33, the material is a listed hazardous waste regardless of the dilution with water or saline because the product still would be the sole active ingredient. If a chemotherapy drug is mixed with diluents and with other pharmaceuticals for use, the unused mixed excess portion can be discarded as a non-hazardous waste. If the chemotherapy drug were listed in 40 CFR, the unmixed excess portion would have to be disposed of as a listed hazardous waste provided the chemotherapy drug is the sole active ingredient in the mixed formulation.

HAZARDOUS WASTE DETERMINATION FOR NON-RCRA HAZARDOUS WASTE (TOXICITY)

CALCULATION FORMULA

Calculated oral or dermal = $\dfrac{100}{\sum_{X=1}^{n} \frac{\%\ A_X}{TA_x}}$

Where:

% A*x* is the weight percent of each toxic compound in the mixture.
TA*x* is the acute oral or dermal LD_{50} or acute oral LD_{LO} of each component.

$\sum_{X=1}^{n}$ is the summation of the calculations, by ingredient

Exercise # 1 **Benadryl Injection**

Active ingredient	**Rat Oral LD_{50} *Toxicity***	**Reference Source**
Diphenhydramine HCL 50 mg/kg.	500 mg/kg	MSDS
	858 mg/kg	Phone call to Manufacturer
	500 mg/kg	Merck Index
	500 mg/kg	RTECS (Registry of Toxic Effects of Chemical Substances)
Dermal Toxicity	No data was found	

Since the toxicity for Benadryl is less than the established oral LD_{50} threshold of 2500 mg/kg, the % weight of the active component must be known to find out if the product must be managed as hazardous waste. This information is obtained from the manufacturer, who states that the active ingredient constitutes 5% of the product.
To determine the actual concentration of Diphenhyldramine in the product, the 5 % is divided by the Rat Oral LD50 obtained from the MSDS (500 mg/kg). This yields a result of 0.01 mg/kg.
To calculate the toxicity of the product, 100 is divided by this result (0.01). The toxicity for Benadryl turns out to be 10, 000 mg/kg.

Oral or dermal= $\dfrac{100}{\frac{5\%}{500\ mg/kg} = 0.01\%} = 10{,}000\ mg/kg$

The calculated oral toxicity is greater than the established oral LD_{50} threshold of 2,500 mg/kg; therefore the pharmaceutical waste is NOT a non-RCRA hazardous waste.

Exercise # 2 Tylenol PM

1) Determine active ingredient: Active ingredients are acetaminophen 500 mg and diphenhydramine HCL 25 mg.

2) Determine toxicity: $\frac{100}{\sum_{X=1}^{n} \frac{\% A_\chi}{TA_x}}$

	Active ingredient		**Reference Source**
	Diphenhydramine HCL	Acetaminophen	
Rat Oral LD50 *Toxicity*	500 mg/kg	N/A	MSDS
	500 mg/kg	N/A	Merck Index
	500 mg/kg	2400 mg/kg	RTECS
Dermal Toxicity: No data was available			

3) Since the toxicity is less than the established oral LD_{50} threshold of 2500 mg/kg, determine the weight % of each active component in the waste pharmaceutical: Manufacturer states the caplet has an average weight of 645mg.

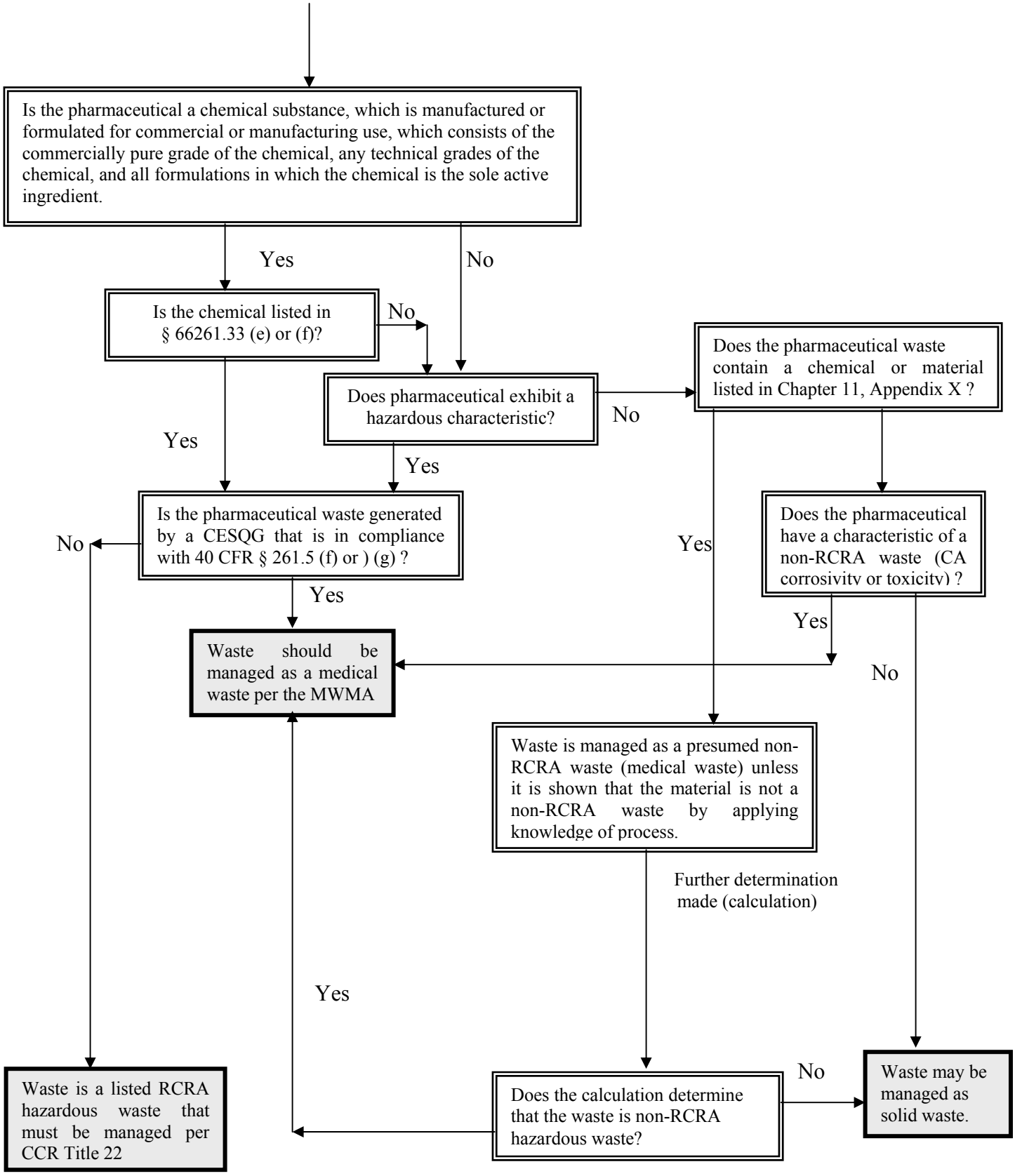
Acetaminophen **500/645 = 77.5 % by weight,**
Diphenhydramine HCL **25 / 645 = 3.8 %by weight.**

4) Calculate oral or dermal toxicity = $\frac{100}{\frac{77.5}{2400} + \frac{3.8}{500}} = 2{,}506.27$ **mg/kg**

$\frac{77.5}{2400} + \frac{3.8}{500} = 0.0323 + 0.0076 = 0.0399$

The calculated oral toxicity is greater than the established oral LD_{50} threshold of 2500 mg/kg; therefore this waste pharmaceutical is NOT a non-RCRA hazardous waste.

Is Pharmaceutical a Hazardous Waste or a Solid Waste?



LISTING	RCRA CHARACTERISTIC	EXAMPLES
D001	**Ignitable**	
	1. Aqueous based liquid with >24 % alcohol	Injectables, cough syrup, tinctures
	2. Non-aqueous liquid with flash point ≤ 140º F	Solvents, non-aqueous injectables
	3. Oxidizers	Whiteners, bleach, peroxides, nitrates
	4. Ignitable compressed gases	Aerosols with propane and/or isobutene
D002	**Corrosive**	
	Aqueous with pH ≤ 2.0 or ≥ 12.5	Acids, bases, depilatories, hydroxides
D003	**Reactive**	
	1. Reacts violently with water	Aerosols are the most common D003 waste.
	2. Generates toxic gases when mixed with water	
	3. Generates cyanide or sulfide bearing gases	
	4. Capable of explosive reaction if heated or under confinement	
	5. Normally unstable	

D004-D043 **Toxic -as determined by the Toxicity Characteristic Leaching Procedure (TCLP)**

	Element of toxicity	TCLP	Examples of Products
D005	Barium	100mg/L	Enemas, colorings
D007	Chromium	5 mg/L	Vitamin/mineral supplements
D009	Mercury	0.2 mg/L	Colorings, nasal/hemorrhoidal/ophthalmic preps, vaccines and injectables. Present as thimerosal, phenyl mercuric nitrate or acetate
D010	Selenium	1 mg/L	Vitamin/mineral supplements, shampoo
D011	Silver	5 mg/L	Creams, applicators
D013	Lindane	0.4 mg/L	Creams, lotions, shampoo
D024	m-Cresol	00 mg/L	Some insulin and other injectables

Examples of products with a sole active ingredient contained on the P or U list

LISTING	ACTIVE INGREDIENT	EXAMPLES
P042	Epinephrine	Injectables
P075	Nicotine and Salts	Chewing gum used to stop smoking
U002	Acetone	Solvent, nail polish remover
U010	Mitomycin C	Antineoplastic, chemotherapy
U035	Chlorambucil	Antineoplastic, chemotherapy
U044	Chloroform	Solvent, anesthetic
U058	Cyclophosphamide	Antineoplastic, chemotherapy
U089	Diethylstilbestrol	Antineoplastic, chemotherapy
U122	Formaldehyde	Preservative, disinfectant
U129	Lindane	Lice control spray, shampoos
U132	Hexachlorophene	Cleansers
U150	Melphalan	Antineoplastic, chemotherapy
U182	Paraldehyde	Sedative, DEA controlled
U188	Phenol	Throat sprays, mouthwash
U200	Reserpine	Antihypertensive
U210	Resorcinol	Keratolytic
U202	Saccharin and salts	Artificial sweeteners
U237	Uracil Mustard	Antineoplastic, chemotherapy
U248/P001	Warfarin and Salts	Anticoagulant